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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/095,639	06/11/1998	PAOLO POZZILLI	515-4111	9860

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EXAMINER	
TON, THAIAN N	

ART UNIT	PAPER NUMBER
1632	21

DATE MAILED: 03/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/095,639	POZZILLI, PAOLO	
	Examiner	Art Unit	
	Thai-An N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants' Amendment, filed 12/18/03, Paper No. 20, has been entered.

Claims 28, 33, 35 and 36 have been amended.

Claims 28-36 are pending and under current examination.

Any rejection made of record in the prior Office action, mailed 6/19/02, Paper No. 16, and not made of record in the instant Office action, has been withdrawn in view of Applicants amendments to the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a dietary product, said product comprising at least one modified bovine beta-casein selected from the group consisting of recombinant or synthetic caseins which lack SEQ ID NO: 1 and SEQ ID NO: 2, and further lack SEQ ID NO: 3 and 4, methods for the inhibition of molecular mimicry of protein GLUT2 comprising the step of administering to newborns and infants an immunogenic infant formula free of caseins which lack SEQ ID NO: 1 and 2, does not reasonably provide enablement for pharmaceutical products comprising at least one modified bovine beta-casein selected from the group consisting of recombinant

or synthetic caseins which lack SEQ ID NO: 1 and SEQ ID NO: 2, and further lack SEQ ID NO: 3 and 4 and methods for inhibiting the inductive effect of beta casein and its fragments on insulin-dependent diabetes comprising administering to newborns and infants an immunogenic infant formula free of caseins which exhibits molecular mimicry with protein GLUT 2, wherein the infant formula lacks SEQ ID NO: 1 and SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

With regard to claim 28, Applicants argue that the claim has been amended to remove the prior recitation, "for the prevention of insulin dependent diabetes" and that the claim as amended now overcomes the basis for the previous rejection. See p. 3, 2nd ¶ of the Response. Applicants' arguments have been carefully considered, however, they are not found to be persuasive. The Examiner agrees that claim 28, as now amended, may be used as a nutrient or dietary product, as stated by Applicant [see p. 3, 2nd ¶ of the Response]; however, the claim additionally recites pharmaceutical product. As such, the term "pharmaceutical" relates to the intended use of the product in a treatment. For reasons of record advanced on pages 5-6 of the prior Office action, the claimed pharmaceutical products are not enabled. In particular, the specification has provided no teachings or evidence to show a correlation between the ingestion of the claimed dietary or pharmaceutical

product and the inhibition of the inductive effect of beta casein on insulin-dependent diabetes.

Applicants further argue that claims 33-36 have now been amended and are now directed to methods of inhibiting the inductive effect of beta casein and its fragments on insulin-dependent diabetes. Applicants argue that the specification discloses the effect of the prevention of insulin dependent diabetes when beta-casein is avoided in the diet of infants and newborns. See p. 3, 3rd ¶ of the Response. Applicants arguments have been considered, however, they are not found to be persuasive. The specification teaches that it is believed that the immune response wherein anti-bovine beta-casein antibodies recognize GLUT2 on immune producing cells leads to the onset of insulin dependent diabetes [see p. 2, lines 13-23]; however, the specification fails to show that administration of the claimed product would result in the inhibition of the inductive effect of beta casein on insulin-dependent diabetes.

Applicants argue that the specification teaches how to use the claimed produce that the modified casein is to be used as an infant food in the same manner as unmodified casein is used. Applicants further argue that the claimed invention is directed to food for newborns and infants and since the prior art methods of feeding casein-based foods to newborns and infants is completely analogous to the feeding of the modified caseins of the present invention, no undue experimentation is required to use the claimed invention. See pp. 4-5 of the Response. Applicants

further argue that the invention is practiced by feeding a specified composition to a specific and identifiable class. Applicants state that in newborns, a diet containing immunogenic caseins has been associated with an increased incidence of insulin-dependent diabetes. See p. 5 of the Response.

Applicants' arguments have been considered, however, they are not found to be persuasive for reasons set forth in the preceding paragraphs. The specification fails to provide teachings, evidence or guidance with regard to a correlation between the feeding of newborns and infants the product as claimed (wherein the product comprises at least one modified bovine case or fragment thereof selected from the group consisting of recombinant or synthetic caseins which lack SEQ ID Nos. 1 and 2) and the inhibition of the inductive effect of beta casein on insulin-dependent diabetes. There is no teachings provided with regard to the target population, for example, which newborns or individuals would be at risk, or would the product be administered to all individuals?

Accordingly, in view of the lack of teachings or guidance provided by the specification with regard to a correlation between the administration of the dietary or pharmaceutical product as claimed and the inhibition of the inductive effect of beta casein or its fragments on insulin-dependent diabetes, it would have required undue experimentation for one of skill in the art to make and/or use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 36 recites a method by obtaining the recombinant human beta casein by cloning methods; however, the claim recites no steps involving gene expression. Appropriate correction is required.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thái-An N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to William Phillips, Patent Analyst, at (703) 305-3482. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

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